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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,365	08/14/2003	Michael S. H. Chu	MIY-P03-024	1647
7590		03/29/2007	EXAMINER	
Patent Group			POUS, NATALIE R	
Ropes & Gray LLP				
One International Place			ART UNIT	
Boston, MA 02110			PAPER NUMBER	
			3731	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/29/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/642,365	CHU ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 8, 11-28 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 11-28 and 30-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/16/06, 3/30/06, 11/22/04</u> .                             | 6) <input type="checkbox"/> Other: ____.                          |

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/16/06 has been entered.

***Response to Arguments***

Applicant's arguments with respect to claims 9, 18, 21 and 27 have been considered but are moot in view of the new ground(s) of rejection based on amendments to the claims. Examiner acknowledges amendment to claims 14 and 26 to correct typographical errors.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

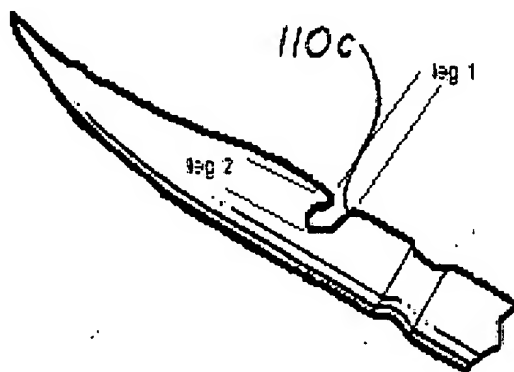
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Malmin (US 4583540).

Regarding Claim 16 Malmin teaches a connector pair for attaching a medical implant to a delivery device, the connector pair comprising, a closed loop

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connector (250) located at the end of a medical implant (240), and a slotted connector (110c) formed in a distal end of a shaft of a delivery device (10) for interfitting with the closed loop connector of the medical implant, the slotted connector including first and second legs, the first leg extending radially into the shaft and the second leg extending axially in a distal direction along the shaft, wherein the second leg is substantially spherical in shape having an opening for accepting the looped connector at an intersection with the first leg (see fig below)



Regarding Claim 18 Malmin teaches a connector pair for attaching a medical implant to a delivery device, the connector pair comprising, a closed loop connector (250) located at the end of a medical implant (240), and a slotted connector (110c) formed in a distal end of a shaft of a delivery device (10) for interfitting with the closed loop connector of the medical implant, the slotted connector including first and second legs, the first leg extending radially into the shaft and the second leg extending axially in a distal direction along the shaft, wherein the second leg includes a curved portion (see fig above)

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 11-13, 21, 22, 23, 24 and 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Giesy et al. (US 5152749) in view of Ferguson et al. (US 3877434)

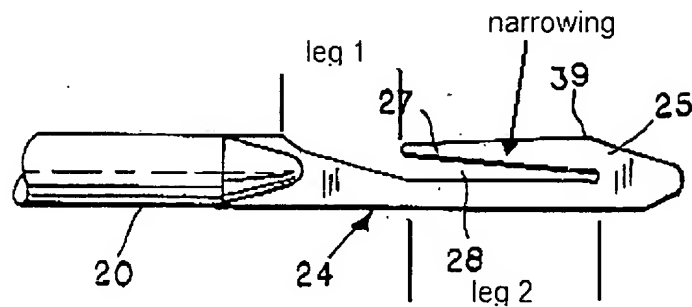
Giesy teaches an implant placement device comprising the following:

- a connector pair (44, 46) for attaching a medical implant (40) to a delivery device (10)
- the connector pair comprising, a closed loop connector (44) located at an end of a medical implant (40)
- a slotted connector (46) formed in a distal end (20b) of a shaft (20) of a delivery device (10)
- for interfitting with the closed loop connector of the medical implant (fig. 3)

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- a freely slidable tubular sleeve (22) on the shaft for sliding over and covering the slotted connector subsequent to interfitting the closed loop connector with the slotted connector (fig. 4).
- the closed loop material is formed from a semi-flexible, shape retaining material (Column 6, proximate lines 50-60).
- the closed loop connector is formed from a suturing material (Column 6, proximate lines 50-60).
- wherein the freely slidable tubular sleeve (22) is sized relative to the shaft so that it is capable of sliding over the slotted connector in response to the shaft being withdrawing from a body of a patient.

Geisy fails to disclose wherein the slotted connector includes first and second legs, the first leg extending radially into the shaft and the second leg extending axially in a distal direction from the first leg along the shaft and being longer than the first leg and includes a narrowing for locking the looped connector into the second leg. Ferguson teaches a device for holding a suture material comprising a slotted connector, wherein the slotted connector includes first and second legs, the first leg extending radially into the shaft and the second leg extending axially in a distal direction from the first leg along the shaft and being longer than the first leg and includes a narrowing (see below)



in order to permit easy insertion of the suture into the opening and to wedge the suture into tight frictional engagement with the device (Column 3, proximate lines 26-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Giesy with a slotted connector as taught by Ferguson in order to permit easy insertion of the suture into the opening and to wedge the suture into tight frictional engagement with the device.

The combination of Giesy and Ferguson further teaches the following limitations

- wherein the second leg is longer than the first leg (see figure above)
- the second leg extends distally at a 90 degree angle to the first leg
- the narrowing is formed where the second leg initially extends from the first leg
- the width of the narrowing is less than that of the loop material

Regarding the limitation wherein the freely slidable tubular sleeve extends past the base portion of the closed loop connector onto the end of the medical implant, Giesy teaches wherein the sleeve extends over the slotted portion in the distal end of the shaft (fig. 4). Since it appears that the device of Giesy performs

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the task of holding the closed loop portion to the end of the shaft equally well and the applicant has not disclosed that extending the sheath past the end of the shaft and onto the end of the medical implant is for any particular purpose or provides any advantage over the embodiment wherein the sleeve extends just over the loop portion, it would have been an obvious matter of design choice to provide the sleeve past the loop portion and onto the implant.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Giesy and Ferguson as applied to claim 21 above, and further in view of Benderev et al. (US 5439467). The combination of Giesy and Ferguson teaches all limitations of preceding dependent claim 21 as previously described, but fails to teach wherein the freely slidable tubular sleeve includes an aperture for aligning with the first leg of the slotted connector during interfitting of with the closed loop connector

Benderev teaches a suture passer comprising a slotted connector with a first leg (160), wherein the device further comprises a slidable tubular sleeve (125) including an aperture (130) in order to securely lock the suture material between the slotted connector and the tubular sleeve. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tubular sleeve of the combination of Giesy and Ferguson with an aperture as taught by Benderev in order to securely lock the suture material between the slotted connector and the tubular sleeve.



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Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Giesy and Ferguson as applied to claim 9 above, and further in view of Skiba (US 6723107). The combination of Giesy and Ferguson teaches all limitations of preceding dependent claim 9, but fails to teach wherein protuberances located in different portions of the slotted connector. Skiba teaches wherein the slotted portion may comprise a number of different configurations (figs 11-17) all with the same goal of securing the loop material in the slotted portion with a narrowing as in fig 16, or a protuberance as in fig 12 wherein the portion at (1206) makes the slot narrower than the loop material (column 3, proximate lines 60-65). Since it appears that the slot structures of the combination of Giesy and Ferguson performs the function of securing the loop material equally well as that disclosed in the application, it would have been an obvious matter of design choice to modify the combination of Giesy and Ferguson with protuberances located in different portions of the slotted portion as taught by Skiba.

Claims 17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmin in view of Ferguson.

Malmin teaches all limitations of preceding dependent claims 16 and 18, but fails to teach wherein the opening in the second leg has a narrowing of less than that of the loop portion of the closed loop connector formed where the second leg initially extends from the first leg. Ferguson teaches wherein the second leg comprises a portion that is narrower in width in order to secure the filament in the leg until the user actively releases it. It would have been obvious

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to one of ordinary skill in the art at the time the invention was made to modify the device of Malmin with a portion in the second leg narrower than the width of the filament in order to secure the filament in the leg until the user actively releases it.

Claims 27, 28 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giesy in view of Skiba.

Giesy teaches a device comprising the following:

- a connector pair (44, 46) for attaching a medical implant (40) to a delivery device (10)
- the connector pair comprising, a closed loop connector (44) located at an end of a medical implant (40)
- a slotted connector (46) formed in a distal end (20b) of a shaft (20) of a delivery device (10)
- for interfitting with the closed loop connector of the medical implant (fig. 3)
- Wherein the slotted connector extends obliquely into the shaft (46) from a first location to a second location, the second location being further distal along the shaft than the first location.

Giesy fails to teach wherein the slotted connector includes a narrowing including protuberances located in different portions of the slotted connector.

Skiba teaches a device for holding a suture, wherein the slotted portion may comprise a number of different configurations (figs 11-17) all with the same goal of securing the loop material in the slotted portion with a narrowing as in fig 16, or a protuberance as in fig 12 wherein the portion at (1206) makes the slot narrower

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than the loop material (column 3, proximate lines 60-65). Since it appears that the slot structures of Skiba perform the function of securing the loop material equally well as that disclosed in the application, it would have been an obvious matter of design choice to modify Giesy as taught by Skiba with protuberances located in different portions of the slotted portion.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP  
3/26/07

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**  
*3/28/07*